

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of using gelatin sponges impregnated with Triparatide on the incidence of dry socket and pain intensity after tooth extraction

#### Protocol summary

##### Study aim

The effect of using gelatin sponges impregnated with Triparatide on the incidence of dry socket and pain intensity after tooth extraction.

##### Design

A clinical trial with a control group (the other side of the same patient's mouth), with parallel groups, double-blind, randomized, phase 3 on 30 patients. The randomization function of Excel software was used for randomization.

##### Settings and conduct

30 patients requiring bilateral molars extraction before dental extraction, are selected and fill out a questionnaire and are evaluated in terms of inclusion and exclusion criteria and systemic diseases. In order to be blind, two A&B containers will be determined by the second instructor except in screening, during the implementation and analysis of the patients' results, in one triparatide solution 250mcg/2.4mL and in the other container the normal solution will be determined. Then, by the first supervisor and the student in the intervention side, gelatin sponges that have been immersed for 8 minutes in a container containing 250mcg/2.4mL Triparatide are placed in socket and sutured in figure of eight and on the control side, gelatin sponge is immersed in normal saline and similar actions are taken. At intervals of 24-72 hours and one week, they will be evaluated using the Visual Analysis System (VAS) chart and objective assessment by the data researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion: Patient with bilateral indication of low molar eruption 18 to 50 y/o Exclusion :: Periapical lesions Poor oral hygiene Smokers Alcoholics Diabetics High blood pressure (>STG 2) Other Systemic Diseases Canned people Pregnant people

##### Intervention groups

A gelatin sponge dipped in Triparatide solution is placed on one side of the patient's mouth in the site of the extracted tooth; and the other soaked in normal saline solution is placed on the other side.

#### Main outcome variables

Pain; Incidence of Dry socket

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230627058604N1**

Registration date: **2023-12-26, 1402/10/05**

Registration timing: **retrospective**

Last update: **2023-12-26, 1402/10/05**

Update count: **0**

##### Registration date

2023-12-26, 1402/10/05

##### Registrant information

##### Name

Ali Choobani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3236 7155

##### Email address

ali.choobani77@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of using gelatin sponges impregnated with Triparatide on the incidence of dry socket and pain intensity after tooth extraction

**Public title**

Triparatide in dry socket and pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients with an indication for the extraction of lower molar teeth bilaterally (split mouth)

**Exclusion criteria:**

Peri apical lesions Poor oral hygiene Smoking Alcoholism Diabetes Hyper tension (stg 2 =<) Other systemic disease Cancerous Pregnancy

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Two containers A and B are marked by the health personnel (the second supervisor of the thesis) that there is normal saline in one and the desired drug in the other. Without knowing the container containing the drug, the main researcher and the executive and the evaluator dipped each of the gelatin sponges in two different containers and placed them in the place of the two extracted teeth on both sides of the participant (for example, solution A is always on the left side of the participant, and solution B is placed on the right side of the patient.) Data analysis and drug effect evaluation are done after the completion of clinical procedures and notification of the principal investigator

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical sciences

**Street address**

No. 144, Shahid Chamran alley, Mofatteh ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5145855359

**Approval date**

2023-09-10, 1402/06/19

**Ethics committee reference number**

IR.TBZMED.REC.1402.425

**Health conditions studied****1****Description of health condition studied**

Pain and incidence of dry socket after tooth extraction

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Dry socket

**Timepoint**

24hours, 72hours and one week after extraxtion

**Method of measurement**

VAS (Visual Analysis System) and objective examination

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: On the side of the intervention (for example, the right side of the patient) and the place of the extracted tooth, a gelatin sponge immersed for 8 minutes in Triparatide solution 250 mcg/2.4 mL belonging to Sina Pharmaceutical Company was placed and a figur of eight suture will be applied and by VAS and objective observation of pain and occurrence of dry socket. It is evaluated at intervals of 24-72 hours and

one week after tooth extraction. Please note that due to the split mouth study, the other side of the patient will be considered as the control group, and normal saline is used instead of Triparatide.

**Category**

Treatment - Drugs

**2****Description**

Considering the split mouth of the other side of the mouth study will be considered as the control group and normal saline will be used instead of triparatide and in double-blind conditions, which will be done in the same way as the intervention side and subsequent examinations.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Department of Surgery, Faculty of Dentistry, Tabriz

**Full name of responsible person**

Ali Choobani

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

Tabriz / Golgasht St. / Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Research and Technology Vice-Chancellor

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research-vice@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farzin Ahmadpour Pournaki

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farzin Ahmadpour Pournaki

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Choobani

**Position**

Phd student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Investigating the effect of triparatide solution on the amount of pain and incidence of dry socket after tooth extraction and all data, including entry and exit criteria, implementation method, study results and documentation, and information of participating patients in a non-identifiable condition with ethical indicators.

**When the data will become available and for how long**

Beginning the access period since mid 2024

**To whom data/document is available**

Due to the need for skill and scientific information in the use of triparatide solution and the ability to make clinical judgment for its use, it will be available only to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Use for systematic review studies Use for clinical strategy Use for retrospective studies Use to conduct similar studies with a new approach

**From where data/document is obtainable**

Vice President of Research and Technology of Tabriz University of Medical Sciences

**What processes are involved for a request to access data/document**

Calling via email or visiting in person to the Vice President of Research and Technology of Tabriz University of Medical Sciences and requesting the use of documents according to the mentioned conditions.

**Comments**